

## **REMARKS**

Claims 1-34 are pending and stand rejected. Claim 30 is objected to. Applicants have amended the drawings. Furthermore, applicants have amended claims 1, 2, 23-25, 29, and 30, and added new claim 35. Reconsideration of the rejection is respectfully requested in view of these amendments and the following remarks.

Applicants respectfully submit that the amendments to claims 1 and 34 can be found in the instant specification at, for example, page 2, lines 27-29, as well as page 34, lines 8-11. Support for new claim 35 can be found in the specification at, for example, the first complete paragraph on page 45.

### **Drawings**

The drawings were objected to because the Action stated that the legend for Figure 2L should be substituted with Figure 3. In response, applicants respectfully submit that the correction should be to the figure labeled as “2I”, as there is no Figure 2L. Applicants have now made this editorial change to sheet 2 of the drawings. Applicants respectfully submit that this change adds no new matter to the present application, as it merely corrects a mislabeling problem.

### **Claim Objections**

Claim 30 was objected to as containing an informality. Applicants respectfully submit that an appropriate correction has now been made.

### **Claim Rejections - 35 USC §112**

Claims 23-25 and 29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that the amendments herein render moot the antecedent basis grounds for rejection of these claims.

By way of a brief review, the claimed invention is directed to an implant for treating tissue within the body of a living being. The implant acts as a scaffold for the in-growth of tissue. It consists of a plurality of components, with at least one of the components including insoluble and fibrous character, and at least one other component including a flowable polymer. The overall implant is plastically deformable.

### **Claim Rejections - 35 USC §102**

Claims 1-34 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication US2002/0183855 to Yamamoto et al. (hereinafter referred to as “Yamamoto”). Applicants respectfully traverse this rejection.

Yamamoto describes an implant for the repair or regeneration of tissue. His implant is three-dimensionally fixed, has shape memory, and maintains physical/structural integrity and porosity after being implanted. As Yamamoto states in Paragraph 31, “The matrix has a shape memory, meaning that it is compressible from its initial size, shape and porosity and

can return from a compressed state to its initial size, shape and porosity.” In contrast, the claimed implant is plastically deformable, meaning that it does not return to its original shape. Among the advantages of being plastically deformable is that the implant can fill irregularly shaped voids (such as in diseased bone or between broken bones) while maintaining substantially uniform properties. In contrast, a purely elastic material having shape memory might relax (expand) more in some regions than in others when filling such a void, giving rise to non-uniform properties such as non-uniform porosity. Also, when the implant is to perform a controlled release of therapeutic agents, a uniform matrix is preferred (see, for example, page 9, lines 14-16 of the instant specification). Non-uniform porosity implies a non-uniform matrix.

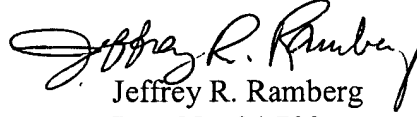
Accordingly, applicants respectfully request that this rejection be withdrawn.

Applicants acknowledge receiving the copy of applicants’ Form PTO-1449, indicating that the examiner has considered the references cited therein.

In view of the above amendments and remarks, applicants respectfully submit that the present application is in condition for allowance. Accordingly, applicants respectfully request issuance of a Notice of Allowance directed to claims 1-35.

Should the Examiner deem that any further action on the part of applicants would be desirable, the Examiner is invited to telephone applicants’ undersigned representative.

Respectfully submitted,

  
Jeffrey R. Ramberg  
Reg. No. 34,700

November 9, 2004

c/o Kensey Nash Corporation  
55 East Uwchlan Avenue  
Exton, PA 19341  
Tel: (610) 594-4392  
Fax: (610) 524-0265

Appendix: (1) Replacement Sheet  
(2) Annotated Sheet Showing Changes

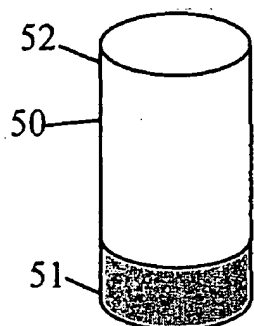
### **AMENDMENTS TO THE DRAWINGS**

The attached sheet of drawings includes changes to Fig. 3. This sheet, which includes Figs. 2G, 2H and 3, replaces the original sheet including Figs. 2G-2I. Figure 2I has been re-labeled as Figure 3.

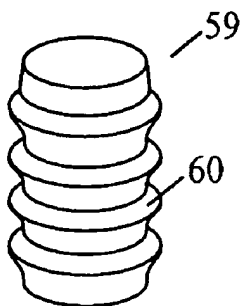
Attachment: Replacement Sheet  
Annotated Sheet Showing Changes



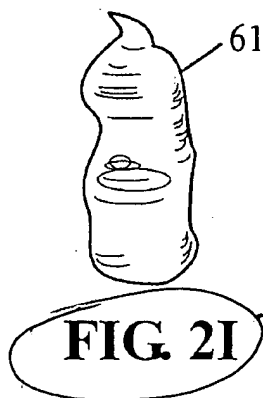
Appl. No. 10/713,438  
Amdt. Dated Nov. 9, 2004  
Reply to Office Action of Aug. 11, 2004  
Annotated Sheet Showing Changes



**FIG. 2G**



**FIG. 2H**



*Figure label changed  
from "Fig. 2I" to  
-- Fig. 3 --*